

Application Serial No.: 10/658,638

**REMARKS**

Claims 1 to 13 and 15 to 38 are pending in the present application. Claim 14 has been canceled without prejudice or disclaimer.

**Claim Rejections Under 35 U.S.C. § 112**

Claims 13 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Particularly, regarding claims 13 and 30, the Office Action sets forth that the phrase "wherein the plurality of compartments include a rest of body compartment" is vague and unclear.

Applicants respectfully submit that a rest of body compartment is clear to one of ordinary skill in the art from a reading of the specification. For example, FIG. 1 and accompanying text describe an exemplary model in which compartment Y represents the rest of body not represented by the other compartments of the model. The rest of body compartment Y has a corresponding equation (7). Thus, the phrase "wherein the plurality of compartments include a rest of body compartment" is clear. Accordingly, Applicants respectfully submit that claims 13 and 30 satisfy the requirements of 35 U.S.C. § 112, second paragraph..

**Anticipation Rejections Based on the Page Patent**

Claims 1 to 9, 12 to 26, 29 to 36, and 38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the U.S. Patent No. 5,199,877 to Page ("the Page patent").

The Page patent is directed to a heart unit that serves as a partial analog system of the human body for demonstrating physiological events which occur during the growth of a brain tumor. The analog device can be used as a teaching aid.

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Claim 1 is directed to a method of mathematically modeling pressure dynamics of a body's intracranial system. The method includes dividing the body into a plurality of compartments and a representation of a heart pump. The plurality of compartments include at least one intracranial compartment and at least one extracranial compartment. Each of the plurality of compartments represent a portion of the body. The representation of a heart pump interacts with at least one of the plurality of compartments. The method also includes deriving a plurality of differential equations, each of the plurality of differential equations governing a pressure dynamic of one of the plurality of compartments. The method further includes solving the plurality of differential equations.

Applicants respectfully submit that the Page patent fails to disclose or suggest a method of mathematically modeling pressure dynamics of a body's intracranial system according to claim 1. The heart unit of the Page patent (see, FIGS. 1A and 1B) is a physical partial analog of the human body. A non-compressible liquid (52) is pumped through the physical system as an analog to blood flowing through certain portions of a human body. The size of a bladder (7) representing a tumor is modified by pumping air into the bladder as an analog to a tumor growth. The bladder (7) resides within a physical cavity (1) that is a simulated cranial cavity. As the tumor size is modified, physical distention (12) in a wall of cavity (1) is observed. The physical distention may act to electrically turn off the analog heart (30) and/or the analog respiratory pump (37). Direct physical pressure measurements may be taken at various pressure meters of the system.

Applicants respectfully submit that the Page patent does not disclose or suggest deriving a differential equation governing a pressure dynamic of a compartment, as required by claim 1. The Page patent even failed to disclose or suggest deriving a differential flow equation corresponding to a compartment, as required by claim 1 prior to the current amendment. In fact, the Page patent does not disclose or suggest the derivation of any differential equation corresponding to a compartment of a mathematical model. The Office Action points to col. 3, lines 1 to 35 as support for the Page patent disclosing "deriving a plurality of differential flow equations, each of the plurality of differential flow equations corresponding to one of the

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plurality of compartments; and solving the plurality of differential flow equations.” (Pages 2 to 3 of the Office Action). However, this cited section of the Page patent only references the derivative  $dV/dt$  as the identity of rate of fluid flow (or volume change over time) of the fluid physically within the heart unit system. The term  $dV/dt$  is only used to define a variable. By definition a derivative over time is a rate. There is no derivation in the Page patent of a differential equation corresponding to a compartment, let alone a derivation of a differential equation governing a pressure dynamic of a compartment, as required by claim 1. The discussion of rates ( $dV/dt$ ) in the Page patent is part of a theoretical discussion of what is happening with the fluid physically within the system during a tumor growth. What is observed by a user of the heart unit system is distention (12) and corresponding shut off of the analog cardiac and/or analog respiratory pumps. There is no disclosure or suggestion of a derivation of a differential equation. Further, the Page patent does not disclose or suggest the solving of a differential equation, let alone the solving of a differential equation governing a pressure dynamic of a compartment, as required by claim 1.

Accordingly, Applicants respectfully submit that for at least these reasons, claim 1 is patentably distinguishable over the Page patent for at least the reasons discussed above.

Claims 2 to 9 and 12, 13, and 15 to 17 depend from claim 1. Thus, claims 2 to 9 and 12, 13, and 15 to 17 are also patentably distinguishable over the Page patent for at least the reasons discussed above with respect to claim 1.

Claim 2 adds the element that at least one of the plurality of differential equations of claim 1 accounts for cerebrovascular autoregulation by the body's sympathetic nervous system. Applicants respectfully submit that the Page patent fails to disclose or suggest a differential equation that accounts for cerebrovascular autoregulation by a body's sympathetic nervous system. The Office Action points to col. 10, lines 45 to 55 of the Page patent as evidence that the Page patent discloses a method wherein at least one of the differential equations accounts for cerebrovascular autoregulation by the body's sympathetic nervous system. However, this section of the Page patent discusses only how measured pressures at pressure meters PI-1 and

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PI-3 may resemble certain hypotension. The section further discusses how the observed pressures differ from prototype brain deformation that has a mechanism that includes "[s]timulus at the brain stem cause impulses which pass through paths in the brain and spinal cord before passing out sympathetic fibers forming peripheral vasomotor nerves." There is no disclosure or suggestion in the Page patent of a differential equation that accounts for cerebrovascular autoregulation by a body's sympathetic nervous system, let alone a differential equation governing a pressure dynamic of a compartment, as required by claim 2. Accordingly, Applicants respectfully submit that claim 2 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 8 adds the element that the plurality of compartments of claim 1 include a plurality of vascular compartments that include a plurality of lower body compartments. Applicants respectfully submit that the Page patent fails to disclose or suggest a lower body compartment. According to the specification of the present application, the "'lower' compartments represent the region below the pelvis." (paragraph [0021]). The "lower" compartments differ from those that are "central," which are those compartments that "represent the region between the lower body and the clavicles and also include extracranial body components above the clavicles but outside of the cranial wall." (paragraph [0021]). The Page patent does not disclose or suggest a compartment representing a region below the pelvis. The Office Action points to col. 5, lines 35 to 42 as evidence that the Page patent discloses a method wherein a plurality of vascular compartments include a plurality of lower body compartments. (page 3). However, this section of the Page patent is referring to cavity 21, which is an analog to a thoracic cavity. The term "lower" appears in this section of the Page patent to refer to the lower portion of cavity (21). When introducing fluid into cavity (21) the fluid flows into the "lower portion" of cavity (21). Cavity (21) is not a lower body compartment, as required by claim 8. Accordingly, Applicants respectfully submit that claim 8 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 9 adds the element that the plurality of lower body compartments of claim 8 represent at least one of the lower arteries, lower capillaries, and lower veins. As discussed above with

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respect to claim 8, the Page patent does not disclose or suggest a lower body compartment, let alone a lower body compartment representing at least one of the lower arteries, lower capillaries, and lower veins, as required by claim 9. Accordingly, Applicants respectfully submit that claim 9 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 12 adds the element that the method of claim 1 further comprises defining an atmosphere compartment, the atmosphere compartment representing a space located outside the body and wherein at least one of the plurality of differential equations of claim 1 accounts for a pressure of the atmosphere compartment. Claim 12 has been amended to clarify its elements as a step in the method of claim 1. Applicants respectfully submit that the Page patent does not disclose or suggest defining an atmosphere compartment, let alone defining an atmosphere compartment wherein at least one of the plurality of differential equations accounts for a pressure of the atmosphere compartment, as required by claim 12. One of the sacs of the heart unit system of the Page patent vents to the atmosphere around the heart unit system when the volume of the injected fluid exceeds capacity. (see, col. 1, lines 58 to 65). However, the atmosphere is not defined as a compartment, nor does a differential equation account for a pressure of the atmosphere. Accordingly, Applicants respectfully submit that claim 12 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 13 adds the element that the plurality of compartments of claim 1 include a rest of body compartment. Applicants respectfully submit that the Page patent does not disclose or suggest a rest of body compartment. The Page patent fails to disclose or suggest a compartment representing portions of the body not specifically represented by another compartment in a model. The Office Action refers to col. 1, lines 58 to 62 as evidence that the Page patent discloses a method wherein the plurality of compartments include a rest of body compartment. (Page 4). However, Applicants cannot find a disclosure or suggestion of a rest of body compartment in this section, or elsewhere, in the Page patent. Accordingly, Applicants respectfully submit that claim 13 is further patentably distinguishable over the Page patent for at least these reasons.

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Claim 14 has been canceled. Thus, the rejection of claim 14 is moot.

Claim 15 adds the element that the at least one of said plurality of differential equations of claim 1 include a term representing pressure flow into and/or out of a corresponding one of said plurality of compartments. Applicants respectfully submit that the Page patent fails to disclose a differential equation that includes a term representing pressure flow into and/or out of a corresponding one of said plurality of compartments, as required by claim 15. The Office Action refers to col. 11, line 20 to col. 12, line 68 as evidence that that Page patent discloses a method wherein the plurality of differential flow equations include a pressure driven flows equation. (Page 4). However, this section, as well as the Page patent as a whole, does not disclose a differential equation governing a pressure dynamic of a compartment, wherein the equation includes a term representing a pressure flow into and/or out of a compartment. Accordingly, Applicants respectfully submit that claim 15 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 16 adds the element that the plurality of differential equations of claim 1 include an equation simulating fluid filtration from capillaries into interstitial space. Applicants respectfully submit that the Page patent does not disclose or suggest interstitial space, let alone an equation that simulates fluid filtration from a capillary to an interstitial space. The Office Action refers to col. 2, lines 60 to 66 as evidence that the Page patent discloses a method wherein the plurality of differential equations include an equation simulating fluid filtration from capillaries into interstitial space. (Page 4). However, this section of the Page patent does not disclose or suggest interstitial space or any differential equations. Fluid (52) flows from cavity (1) through variable orifice/filter (13), which is an analog "capillary system of brain tissue." The fluid then flows through line (19), which is an analog venous system, to chamber 21, which is an analog "thoracic cavity central venous pools." There is no disclosure or suggestion here (or elsewhere in the Page patent) of fluid filtration from a capillary into interstitial space. Further, the Page patent does not disclose or suggest an equation simulating such fluid filtration. Accordingly, claim 16 is further patentably distinguishable over the Page patent for at least these reasons.

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Independent claim 18 is directed to a system for modeling an intracranial system. The system includes a body compartment module adapted to divide the body into a plurality of compartments and a representation of a heart pump. The plurality of compartments include at least one intracranial compartment and at least one extracranial compartment. Each of the plurality of compartments represent a portion of the body. The system also includes an equation module adapted to derive a plurality of differential equations, each of the plurality of differential equations govern a pressure dynamic of one of the plurality of compartments. The system further includes an equation solver module adapted to solve the plurality of differential equations.

Applicants respectfully submit that the Page patent fails to disclose or suggest a system for modeling an intracranial system according to claim 18. As discussed above with respect to claim 1, the Page patent does not disclose or suggest the derivation of a differential equation governing a pressure dynamic of a compartment, let alone an equation module adapted to derive such a differential equation, as required by claim 18. Further, as discussed above with respect to claim 1, the Page patent does not disclose or suggest the solving of a differential equation, let alone an equation solver module adapted to solve a differential equation, as required by claim 18. Accordingly, Applicants respectfully submit that claim 18 is patentably distinguishable over the Page patent for at least these reasons.

Claims 19 to 25 and 29 to 33 depend from claim 18. Thus, claims 19 to 25 and 29 to 33 are patentably distinguishable over the Page patent for at least the reasons discussed above with respect to claim 18.

Claim 19 adds the element that at least one of the plurality of differential equations of claim 1 accounts for cerebrovascular autoregulation by the body's sympathetic nervous system. As discussed above with respect to claim 2, the Page patent does not disclose or suggest a differential equation that accounts for cerebrovascular autoregulation by a body's sympathetic nervous system, as required by claim 19. Accordingly, Applicants respectfully submit that claim 19 is further patentably distinguishable over the Page patent for at least these reasons.

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Claim 25 adds the element that the plurality of compartments of claim 18 include a plurality of vascular compartments that include a plurality of lower body compartments. As discussed above with respect to claim 8, the Page patent fails to disclose or suggest a lower body compartment. Accordingly, Applicants respectfully submit that claim 25 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 26 adds the element that the plurality of lower body compartments of claim 25 represent at least one of the lower arteries, lower capillaries, and lower veins. As discussed above with respect to claim 25, the Page patent does not disclose or suggest a lower body compartment, let alone a lower body compartment representing at least one of the lower arteries, lower capillaries, and lower veins, as required by claim 26. Accordingly, Applicants respectfully submit that claim 26 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 29 adds the element that the system of claim 18 further comprises an atmosphere compartment, the atmosphere compartment representing a space located outside the body and wherein at least one of the plurality of differential equations of claim 18 accounts for a pressure of the atmosphere compartment. As discussed above with respect to claim 12, the Page patent does not disclose or suggest an atmosphere compartment wherein at least one of the plurality of differential equations accounts for a pressure of the atmosphere compartment, as required by claim 29. Accordingly, Applicants respectfully submit that claim 29 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 30 adds the element that the plurality of compartments of claim 18 include a rest of body compartment. As discussed above with respect to claim 13, the Page patent does not disclose or suggest a rest of body compartment. Accordingly, Applicants respectfully submit that claim 30 is further patentably distinguishable over the Page patent.

Claim 31 adds the element that the at least one of said plurality of differential equations of claim 18 include a term representing pressure flow into and/or out of a corresponding one of said

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plurality of compartments. As discussed above with respect to claim 15, the Page patent fails to disclose a differential equation that includes a term representing pressure flow into and/or out of a corresponding one of said plurality of compartments, as required by claim 31. Accordingly, Applicants respectfully submit that claim 31 is further patentably distinguishable over the Page patent for at least these reasons.

Claim 32 adds the element that the plurality of differential equations of claim 18 include an equation simulating fluid filtration from capillaries into interstitial space. As discussed above with respect to claim 16, the Page patent does not disclose or suggest interstitial space, let alone an equation that simulates fluid filtration from a capillary to an interstitial space. Accordingly, claim 32 is further patentably distinguishable over the Page patent for at least these reasons.

Independent claim 34 is directed to a method of modeling pressure dynamics of an intracranial system. The method includes dividing a body into a plurality of compartments and a representation of a heart pump. Each of the plurality of compartments represent a portion of the body. The plurality of compartments include at least one intracranial compartment and at least one extracranial compartment. The representation of a heart pump interacts with at least one of the plurality of compartments. The method also includes deriving a plurality of differential equations, each of the plurality of differential equations governing a pressure dynamic of one of the plurality of compartments. At least one of the differential equations accounts for cerebrovascular autoregulation by a sympathetic nervous system. The method further includes solving the plurality of differential equations.

Independent claim 35 is directed to a method of modeling pressure dynamics of an intracranial system. The method includes dividing a body into a plurality of compartments, each of the plurality of compartments representing a portion of the body. The plurality of compartments include at least one intracranial compartment and at least one extracranial compartment. The method also includes providing a means for representing a heart pump that interacts with at least one of the plurality of compartments. The method further includes deriving a plurality of differential equations, each of the plurality of differential equations governing a pressure

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dynamic of one of the plurality of compartments. At least one of the differential equations includes a means to account for cerebrovascular autoregulation by a sympathetic nervous system. The method still further includes solving the plurality of differential equations.

Applicants respectfully submit that the Page patent fails to disclose or suggest a method of modeling pressure dynamics of an intracranial system according to either claim 34 or claim 35. As discussed above with respect to claim 1, the Page patent does not disclose or suggest the derivation of a differential equation governing a pressure dynamic of a compartment. Further, as discussed above with respect to claim 1, the Page patent does not disclose or suggest the solving of a differential equation. As discussed above with respect to claim 2, the Page patent does not disclose or suggest a differential equation that accounts for cerebrovascular autoregulation by a body's sympathetic nervous system. Accordingly, Applicants respectfully submit that claims 34 and 35 are patentably distinguishable over the Page patent for at least these reasons.

Independent claim 36 is directed to a method of modeling pressure dynamics of an intracranial system. The method includes providing a means for dividing a body into a plurality of compartments and a representation of a heart pump, each of the plurality of compartments representing a portion of the body. The plurality of compartments include at least one intracranial compartment and at least one extracranial compartment. The representation of a heart pump interacts with at least one of the plurality of compartments. The method also includes providing a means for deriving a plurality of differential equations, each of the plurality of differential equations governing a pressure dynamic of one of the plurality of compartments. The method further includes providing a means for solving the plurality of differential equations.

Applicants respectfully submit that the Page patent fails to disclose or suggest a method of modeling pressure dynamics of an intracranial system according to claim 36. As discussed above with respect to claim 1, the Page patent does not disclose or suggest the derivation of a differential equation governing a pressure dynamic of a compartment, let alone providing a means for deriving such a differential equation, as required by claim 36. Further, as discussed above with respect to claim 1, the Page patent does not disclose or suggest the solving of a

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differential equation, let alone providing a means for solving such a differential equation, as required by claim 36. Accordingly, Applicants respectfully submit that claim 36 is patentably distinguishable over the Page patent for at least these reasons.

Independent claim 38 is directed to a mathematical model for simulating pressure dynamics of an intracranial system. The mathematical model includes a means for dividing the body into a plurality of compartments and a representation of a heart pump, each of the plurality of compartments representing a portion of the body. The plurality of compartments include at least one intracranial compartment and at least one extracranial compartment. The mathematical model also includes a means for deriving a plurality of differential equations, each of the plurality of differential equations governing a pressure dynamic of one of the plurality of compartments. The mathematical model further includes a means for solving the plurality of differential equations.

Applicants respectfully submit that the Page patent fails to disclose or suggest a mathematical model for simulating pressure dynamics of an intracranial system according to claim 38. As discussed above with respect to claim 1, the Page patent does not disclose or suggest the derivation of a differential equation governing a pressure dynamic of a compartment, let alone a means for deriving such a differential equation, as required by claim 38. Further, as discussed above with respect to claim 1, the Page patent does not disclose or suggest the solving of a differential equation, let alone a means for solving such a differential equation, as required by claim 38. Accordingly, Applicants respectfully submit that claim 38 is patentably distinguishable over the Page patent for at least these reasons.

#### **Obviousness Rejections Based on the Page Patent**

Claims 10, 11, 27, 28, and 37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Page patent.

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Claim 10 depends from claim 1 and adds the element that the plurality of compartments of claim 1 include a plurality of non-vascular compartments. Claim 27 depends from claim 18 and adds the element that the plurality of compartments of claim 18 include a plurality of non-vascular compartments. As discussed above with respect to claim 1 and 18, the Page patent fails to disclose each and every element of claims 1 or 18. Even if it were obvious to one of ordinary skill in the art to modify the non-vascular compartment described in the Page patent by providing a plurality of non-vascular compartments (which Applicants do not admit here), as set forth in the Office Action, such a modification would not cure the deficiencies of the Page patent with respect to the elements of claim 1 or 18. Accordingly, Applicants respectfully submit that claims 10 and 27 are patentably distinguishable over the Page patent and the knowledge of one of ordinary skill, either alone or in combination, for at least these reasons.

Claim 11 depends from claim 10. Claim 28 depends from claim 27. Each of claims 10 and 27 add the element that the plurality of non-vascular compartments of claims 10 and 27, respectively, represent at least one of the lower tissue, brain, ventricular CSF, and extra-ventricular CSF.

Applicants respectfully submit that the Office Action fails to point to any prior art reference or combination of prior art references that discloses or suggests a method wherein a plurality of non-vascular compartments represent at least one of the lower tissue, brain, ventricular CSF, and extra-ventricular CSF, as required by claims 11 and 28. The Office Action simply reiterates the claim language of claims 11 and 28. Accordingly, the Office Action has not presented a prima facie case of anticipation or obviousness for either claims 11 or 28. Accordingly, Applicants respectfully submit that claims 11 and 28 are in a condition for allowance.

Independent claim 37 is directed to method of modeling pressure dynamics of a body's intracranial system. The method includes dividing the body into a plurality of compartments and a representation of a heart pump, each of said plurality of compartments representing a portion of the body. The plurality of compartments include at least one intracranial compartment and at least one extracranial compartment. The representation of a heart pump interacts with at least

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one of said plurality of compartments. A plurality of the plurality of compartments are vascular and a plurality of the plurality of compartments are non-vascular. The vascular compartments include at least one of the intracranial arteries, intracranial capillaries, choroids plexus capillaries, venous sinus jugular veins, intracranial veins, central arteries, central capillaries, central veins, extra-ventricular CSF, lower arteries, lower capillaries, and lower veins. The non-vascular compartments include at least one of lower tissue, brain, ventricular CSF, and extra-ventricular CSF. The method also includes deriving a plurality of differential equations, each of the plurality of differential equations governing a pressure dynamic of one of the plurality of compartments. The method further includes solving the plurality of differential equations.

As discussed above with respect to claim 1, the Page patent fails to disclose or suggest the derivation of a differential equation governing a pressure dynamic of a compartment, as required by claim 37. Also as discussed above with respect to claim 1, does not disclose or suggest the solving of a differential equation, as required by claim 37. Further, even if it were obvious to one of ordinary skill in the art to modify the non-vascular compartment described in the Page patent by providing a plurality of non-vascular compartments (which Applicants do not admit here), as set forth in the Office Action, such a modification would not cure the deficiencies of the Page patent. Accordingly, claim 37 is patentably distinguishable over the Page patent and the knowledge of one of ordinary skill, alone or in combination, for at least these reasons.

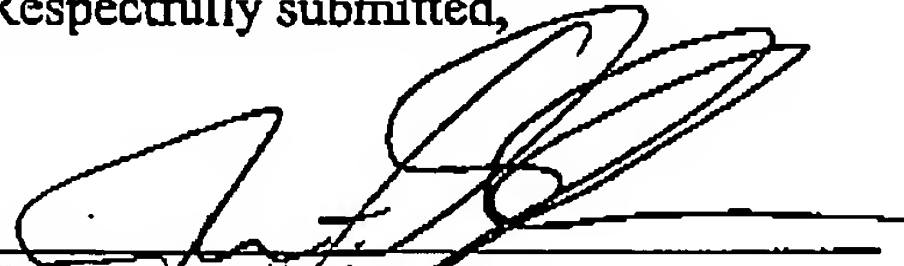
Additionally, Applicants respectfully submit that, as discussed above with respect to claims 11 and 28, the Office Action fails to point to any prior art reference or combination of prior art references that discloses or suggests a method wherein a plurality of non-vascular compartments represent at least one of the lower tissue, brain, ventricular CSF, and extra-ventricular CSF, as required by claim 37. Accordingly, Applicants respectfully submit that the Office Action has not set forth a prima facie case for anticipation or obviousness of claim 37 and that claim 37 is in a condition for allowance.



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Accordingly, Applicants submit that all claims are in a condition for allowance and respectfully solicit the prompt issuance of a Notice of Allowance. If any issues remain, the Examiner is encouraged to call the undersigned attorney at the number listed below.

Respectfully submitted,



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